Certification:

As Investigator, I certify:

a. The information submitted to the IRB is true and correct to the best of my knowledge.
b. All co-investigators, collaborating physicians and all others assisting with the study have been thoroughly and completely trained in all aspects of this study.
c. I am aware of my recordkeeping responsibilities regarding this study and am responsible for maintaining all records in accordance with Federal Regulations.
d. I will keep on file (for at least six years from the project completion date) and make available, on request by the IRB, copies of signed Informed Consent Forms of all subjects participating in this research.
e. I will comply with the Policies and Procedures of the INTEGRIS Health Inc. Institutional Review Board and with the regulations governing clinical investigations set forth in the Code of Federal Regulations.
f. I have been given a copy of the Policies and Procedures of the INTEGRIS Health Inc. Institutional Review Board.
g. I, and all co-investigators collaborating on the study, have completed the mandatory training required in human research.
h. I understand that I am obligated to protect and keep confidential any identifiable, private information gathered about individual subjects through the conduct of my research; and I agree to keep such information confidential, unless I obtain the subject's express written permission to do otherwise.
i. Any medical procedures or medical treatments of human subjects for the purposes of the present research will be performed by, or under the supervision of, a person who is 1) licensed or certified to perform that particular procedure and 2) who holds delineated clinical privileges to perform that particular procedure.
j. If there are any changes, modifications, or revisions either in the research protocol, title or names of Researchers, the IRB must be immediately notified and prior permission must be received before proceeding.
k. Any project which exceeds a period of one (1) year in duration must be reviewed and receive IRB approval prior to the beginning of the second and any successive years of the research project. It is the responsibility of the Principal Investigator to submit a Request for Continuing Review approximately two (2) months prior to the expiration date of the existing approval and to ensure that a Final Report is filed when the project is completed
l. Where the Application for Protocol Approval includes a Request For Waiver of Authorization for Research, please accept my signature below as a written assurance that the referenced protected health information will not be re-used or disclosed to any other person or entity except as described in the application, unless specifically authorized by this IRB or by the subject of the PHI.

_____ _____

Principal Investigator Date